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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
	)	Criminal No. 21-129
v.	)	
	)	(21 U.S.C. §§ 331(c), 333(a)(1))
BRIAN ISBELL	)	

INFORMATION

The United States Attorney charges:

COUNT ONE

At all times material to this Information:

Introduction

1. The United States Food and Drug Administration ("FDA") was an agency of the United States government entrusted with protecting the health and safety of the public by enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 et seq. ("the Act"). The Act was also implemented and defined by various provisions of the Code of Federal Regulations ("C.F.R."). The FDA's responsibilities under the Act included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce.

2. The Act defined "drugs" to include articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; articles other than food intended to affect the structure or any function of the body of humans; and articles intended for use as a component of such articles. 21 U.S.C. § 321(g)(1).

3. The receipt in interstate commerce of any misbranded drug, and the delivery or proffered delivery thereof for pay or otherwise, was prohibited. 21 U.S.C. § 331(c). A drug was

misbranded where its labeling was false or misleading in any particular, 21 U.S.C. § 352(a); or where its labelling did not bear adequate directions for use, 21 U.S.C. § 352(f)(1).

Relevant Substances

4. Benzodiazepines were a class of drugs that produced central nervous system depression. Physicians could prescribe FDA-approved benzodiazepines to treat insomnia and anxiety, but benzodiazepines also carried risks of dependency, toxicity, and even fatal overdose, particularly when combined with other central nervous system depressants.

5. Flubromazolam was a benzodiazepine derivative that carried increased risk of harm to users due to its ability to produce strong sedation and amnesia at low doses.

6. The FDA had not approved any drugs containing flubromazolam in the United States, and as a result, they could not be legally distributed in the United States for use as a drug.

Receipt and Delivery of Flubromazolam

7. From on or about May 10, 2018, to on or about June 7, 2018, in the Western District of Pennsylvania, the defendant, BRIAN ISBELL, having received in interstate commerce a misbranded drug, did deliver and cause the delivery of such misbranded drug for pay and otherwise, to wit: having received from Canada flubromazolam, a drug that was misbranded in that its labelling identified it as a different drug and lacked adequate directions for use, BRIAN ISBELL delivered such drug to customers for pay and otherwise.

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1).

STEPHEN R. KAUFMAN
Acting United States Attorney
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